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TITLE OF THE INVENTION (280 characters max)

A DEVICE FOR GAIT SYNCHRONIZED VIBRATORY STIMULATION OF THE FEET

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ENCLOSED APPLICATION PARTS ***(CHECK ALL THAT APPLY)***

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[X] Small Entity status is entitled to be, and hereby is, asserted for this application

[ ] Drawing(s) Number of sheets [ ]

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[X] A check in the amount of $80.00 is enclosed to cover the Provisional Filing Fee

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PROVISIONAL APPLICATION FILING ONLY

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ENTITLED

A DEVICE FOR GAIT SYNCHRONIZED VIBRATORY STIUMULATION OF THE FEET

BY

PETER NOVAK

EXPFRESS MAIL NO: EV 044751286 US

A Device for Gait Synchronized Vibratory Stimulation of the Feet.

Peter Novak, Dep. Neurology, BMC, February 11, 2003 P. Novak

a. General purpose of invention.

This invention is related to a design of a device that enables to stimulate the foot propriocetors in synchrony with the phase of the gait for the purpose to improve the gait.

Somatosensory feedback plays a critical role in the control of movement, balance and gait. It was shown that alterations of the proprioceptive feedback can alter balance, posture and/or gait [1-5]. For example, vibratory stimulation of muscles facilitates voluntary muscle contractions via proprioceptive feedback. Vibratory stimulation of the foot elicits postural responses that control maintenance of the erect posture. Vibration of the feet with noise-like character improves motor control in humans by reducing the postural sway. Vibrators applied to calf muscles or with galvanic vestibular stimulation enhances recovery of postural functions in post stroke patients.

The shortcoming of commonly used approaches is that they do not take into account the phase of the gait. Naturally, the foot proprioceptors are activated upon the foot step and deactivated upon the elevation of the foot. As such a device that delivers the vibration stimulus at a particular phase of the gait could enhance the beneficial effect of vibratory stimulation upon the gait.

b. Technical description of invention.

The device delivers a vibratory stimulus that is synchronized with the phase of the gait. The device senses the foot pressure, upon satisfying predetermined conditions (for example certain pressure level) it delivers the vibration stimulus to the foot (Fig 1). As vibrator stimulator an electric motor with an eccentric load or piezo based vibrator can be used. In the simplest form, the device consists from a footswitch that turns on the vibration motor upon the foot step. The device consisting from the micro switch and miniature vibrator motor with eccentric load "pager motor", (Namiki, Japan, diameter 4 mm) is implantable inside the shoes. The device is embodied into the plastic enclosure of the size 2.5 x 2.5 x 0.8 cm. Typically, two units are installed into one shoe, one below the heel and a second below the fore heel.

The whole unit is inserted into the modified shoes. It is very simple in use and it is non-invasive.

c. Advantages and improvements over existing methods, devices or materials

The advantage of the invented device is that the vibratory stimulation is synchronized with the phase of the gait. The pulsatile stimulation reduces habituation of the proprioceptors and prolonges the battery life.

d. Possible variation and modifications.

The device in its simplest form consist from the footswitch and vibrator motor. The design is simple and it is easy to manufacture device in large quantities.

More advanced device will accommodate the timer that will turn off the vibration after predefined delay to prevent continuous stimulation when the subject stands without movement or sits. Improved control can be achieved by using the pressure sensors that gives the output signal proportional to the pressure at the sole. This pressure signal can be processed by a microcontroller/microprocessor, sampled typically using the analog/digital converter. After processing the microprocessor controls the vibrator motor, typically via digital/analog converter or other interface.

Microcontroller/microprocessor based system enables considerable flexibility in controlling of the desired vibratory stimulus in terms of gait phase, stimulus duration and intensity as well as interrelation between 2 stimuli when more than one vibratory device is used. Variety of stimulatory patterns can be employed such as a preemptive stimulation (typically short time before the foot touches the floor) to facilitate response of the locomotory apparatus, stimulation of the fore heel that is phase-shifted from below-heel stimulation and phase-correlated stimulation of contralateral foot.

e. Features believed to be new.

The new features of the device is synchronization of the vibratory stimulation with the phase of the gait.

f. Close or related patents

Unknown

g. Problem solved

Working prototype of the device is available.

h. Possible use of invention

Treatment of variety of gait disorders such as primary gait disorders, gait disorders associated with systemic illness, gait disorders associated with stroke, Parkinson's disease, dementia, multiple sclerosis, aging, etc.

i. Disadvantage or limitations

Device is battery operated, necessitating recharging/replacement of the batteries. The prototype is not waterproof, thus it is not suitable for outdoor use. The latter limitation as a minor since it can be addressed using available technologies. For more advanced device controlled with microprocessor/microcontroller, the additional electronics might pose an additional constrains on the battery life and can increase the cost and complexity of the device.

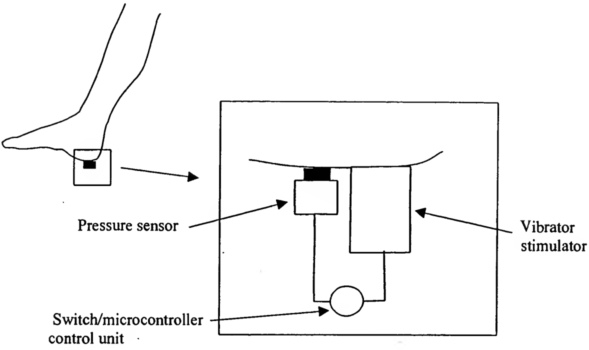
j. State of the development.

The functional prototype is ready for use.

k. Prospective commercial interest.

The device in its simplest form is extremely cost effective. The estimated wholesale price of one unit is below $2.00, even this can be substantially reduced if builded in large quantities. (probably below $ 0.5 - $ 1.0.). The potential marked is enormous, estimated number of subjects that might benefit from the device is in order of millions in US only.

Appendix. 1
Figure 1. Schematic drawing:



Appendix 2.
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Vibratory Stimulation of the Soles Synchronized with the Step Reduces Gait Variability in Healthy Volunteers.

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Abstract
Increased stride-to-stride variability has been associated with neurological gait abnormalities as wells as falls. Previous studies suggested that alterations of the proprioceptive feedback using vibratory stimulation may affect the gait. The objective of our study was to assess effects of vibratory stimulation of the soles synchronized with the step on the gait variability. Step-synchronized vibratory stimulation (GSV) of the soles was evaluated in 7 healthy subjects (4 females and 3 males, age range 28-53 years) during self-paced normal walk. The GSV order (on/off) was random for each 6 minute walking trial. Stride-to-stride interval was measured using force foot-switches connected to a wearable computer. The device for GSV was mounted into shoe insoles. The vibratory device operates in the closed-loop mode and it is activated upon heel strike and turned off during push off phase. GSV decreased standard deviation ($p<0.014$) and coefficient of variation ($p<0.016$) of the gait while there was no statistical difference in other monitored parameters (walking distance, average speed and step duration, average step length). It is concluded that the closed-loop step-synchronized vibratory stimulation of the soles reduced the stride-to-stride variability in healthy controls. Since the stride-to-stride variability is positively correlated with gait abnormalities the presented approach might be useful for treatment of the gait disorders.

Keywords: gait variability, vibratory stimulation, soles

Introduction

Alteration of the proprioceptive feedback using vibratory stimulation may affect balance, posture and gait. In healthy volunteers, plantar stimulation results in a body tilt, affects the postural adjustment to upright posture [14,15,16] and may improve balance [22,23,27]. Vibratory stimulation of the leg muscles facilitates voluntary muscle contractions [4]. Increase in walking speed was observed during continuous vibration of the neck [11] and hamstring muscles [12]. Effectiveness of the vibratory stimulation depends upon the phase of the gait, such as it is more effective during the swing phase as compared to stance phase [12]. Moreover, vibration of the biceps femoris tendon affects the interlimb coordination [30].

Sensory stimulation was already explored in treatment of several neurological conditions associated with movement abnormalities. For example, vibratory stimulation of muscle tendons can reduce parkinsonian tremor [13]. Vibrators applied on the calf muscles facilitate recovery of postural control in post-stroke patients [18]. Plantar stimulation improves the rightward orientation in patients with spatial neglect after the right hemispheric stroke [24].

To assess the effects of vibratory stimulation on gait, we designed a wearable vibratory device that can be used during normal walking. The mechanoreceptors of the soles that mediate postural adjustment are sensitive to vibratory stimulation [15] and the pressure created during the stance phase of the step activates these receptors [29]. In analogy, we have designed a device that delivers a vibratory stimulus to the sole while the foot is in contact with the floor.

Material and methods.

Seven healthy volunteers, 4 women, 3 men, age range 28-53 years, without history of neuromuscular disorders, gait and foot abnormalities participated in the study. The Institutional Review Board of the Boston University approved the study and all subjects signed a written consent.

In house developed, wearable, battery operated device that gives a vibratory stimulus synchronized with stance phase of the gait was designed. The vibratory device (VD, Fig. 1) senses the pressure at the sole and turns on vibration alert upon heel touch and turns off upon push off during swing phase. VD was mounted in the shoe insoles that can be inserted into regular shoes. The stimulus intensity was empirically set to near-threshold level. Vibration threshold was not formally evaluated for all our subjects. The subjects felt the stimulation slightly while standing. Upon walking, the subjects did sense vibration typically only when specifically asked to focus on vibratory sensation at feet.
Subjects were asked to walk for 6 minutes at their normal speed in the hallway (length 73 m, width 1.7 m) with the device on and 6 minutes with the device turned off. To reduce expectation bias and to check subjective level of vibratory stimulation, subjects we allowed to walk for few steps with device on and off before the gait recordings.
The order of stimulation was selected randomly. The investigator followed all subjects as a safety precaution.

The gait characteristics were recorded using a gait monitoring system (Gait Logger, JAS Research Inc, MA) connected to the foot switches (B&L Engineering Inc.,

CA), using four force sensors at each foot. The gait signal was sampled 200 Hz using 12 bits analog/digital converter and recorded on the portable microcontroller-based storage device. The raw data were transferred to a personal computer and processed off-line using software written in Matlab® 6.1 (The MathWorks, Inc., MA). The heel-touch was detected for each step forming stride-to-stride interval time series. Values exceeding two standard deviations were excluded. The following parameters were further analyzed: average step length, walking distance, average speed, standard deviation (SD) and coefficient of variation (CV, 100 x sd/mean step duration) of the stride-to-stride interval. CV is an index of variability normalized to a subject's mean step length. For statistical analysis we used average SD of both legs. Statistical analysis was performed using JPM 5.0.1 (SAS Institute 2003) using ANOVA for repeated measures with vibration (off versus on) as an independent variable.

Vibratory Device-Description

The vibratory device (Fig.1) utilizes miniature vibrating disk motor Optec 2890W11 (OPTEC Co. Ltd., Japan) vibrating at frequency 70 Hz and operating at 1.3 V. The foot sensor that provides a feedback to the vibratory device is based on home made membrane switch that turns on upon approximate force 350 g. The foot sensor was glued on top of the vibration motor enclosure. The whole unit was embedded in the plastic foam insoles. For each insole, two vibratory units were used, below the heel and below the forefoot. In this paper, the results with the device operating in simple closed loop mode are presented. The device provides all necessary input/output signals for interfacing with the real-time microcontroller that might deliver the vibratory stimulation in a variety of preprogrammed patterns.

Results

The device was well tolerated. Six minutes of walking periods included the straight segments and typically 6–7 turns of 180 degree. Figure 2 shows an example of the stride-to-stride intervals with the vibratory stimulation on and off during walking in one healthy subject. SD decreased during walking with vibration. Gait characteristics during vibration on and off are summarized in the Table 1. The vibratory stimulation decreased SD of the stride-to-stride interval ($P<0.014$) and CV ($P<0.016$) while there was no statistical difference in other monitored parameters (walking distance, mean gait speed, mean step length, step duration). Figure 3 shows an effect of SD with vibration device on compared to device off for all subjects. The reduction of SD and CV was observed in all subjects except of one. In that subject the baseline SD was the lowest (15.4 ms) of all subjects and it increased slightly to 16.7 ms during vibration.

Discussion

The main finding of our study is that the vibratory stimulation of the soles that is phase-synchronized with the step reduces the gait variability in healthy volunteers.
The physiological mechanisms underlying the effect of the vibratory stimulation are complex and it may include both spinal and cerebral circuits. Vibratory stimulation of a muscle tendon results in contraction of the muscle and relaxation of the antagonist

muscle [6]. The effect is much more pronounced in the contracted muscle as compared to relaxed muscle, it depends upon the vibratory frequency and length of the stimulation [6] and it is context dependent [26]. During standing, vibratory stimulation of the heel induces forward postural sway, stimulation of the forefoot results in the backward tilt, while simultaneous stimulation at both foot areas has no net effect [15]. It was suggested that the postural response to vibratory stimulation is CNS mediated [15]. Functional MRI studies showed activation of a distinct brain structures during vibratory stimulation. Stimulation of digit tips activates the contralateral primary somatosensory cortex, bilateral secondary somatosensory cortex, the precentral gyrus, the posterior insula, the posterior parietal region and the posterior cingulate [3]. PET studies showed that vibratory stimulation of the metacarpal joints activates ipsilateral sensory cortical areas and contralateral basal ganglia [2].

The vibratory device in our study operated in a closed loop mode that results in amplification of the sensory feedback. In general, sensory feedback facilitates adjustment of limb trajectories during each step [21] and participates in smoothing of walking irregularities [5]. As such vibratory stimulation of soles may modulate a motoneuron output in a similar way than electrical [1] or mechanical [15,17] stimulation of the foot. In particular we hypothesize that the ankle extensors are activated during the heelstrike when the posterior vibratory device turns on followed by activation of the ankle flexors upon the touch of the forefoot with activation of the anterior vibratory stimulator. These responses are most likely mediated at both spinal and at the cerebral level, the latter being more important as suggested by posturographic studies [15].

There is accumulating evidence that the stride time variability is a good measure of gait unsteadiness. The stride-to-stride variability is increased in the subjects with history of falls [20,19,7,8,9] and it is an independent predictor of falling [19]. Our data suggest that the vibratory stimulation of the soles operating in the closed-loop mode may improve the gait profile by reducing the gait variability and therefore it might be useful for treatment of the gait and balance disorders. An advantage of the proposed approach is that it does not require a conscious attention to be effective. This might be important when there are reduced attentional resources available for the postural tasks such as in elderly subjects [28], in subjects with Alzheimer's disease [25] or in Parkinson's disease [10].

In conclusions our data suggest that the presented approach might be useful in the treatment of the walking and balance abnormalities. We also believe that the study of an effect of the vibratory stimulation that is synchronized with the step might provide an additional insight in the complex dynamic of walking.

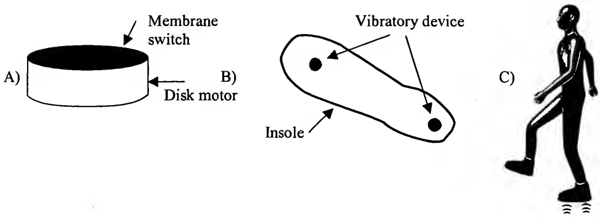

Figure 1. Schematic diagram of the vibratory device. A), Vibratory device consists from a vibration disk motor, diameter 18 mm and a membrane switch glued on the top of the motor with resulting thickness ~ 5.0 mm and weight ~ 5 grams; B) Insole with the build-in vibration device; C) Shoes with vibratory devices.

Gait parameters	Vibration		p
	Off	On	
Walking distance (m)	525.8±59.7	524.1±55.32	NS
Mean gait speed (m/s)	1.46±0.16	1.45±0.15	NS
Mean step length (m)	1.71±0.48	1.5±0.1	NS
SD (ms)	22.92±5.03	19.93±3.57	0.014
CV (%)	2.2±0.63	1.9±0.46	0.016
Step duration (ms)	1024.45±33.06	1020.86±85.17	NS

TABLE 1 Descriptive statistic. NS= not significant.

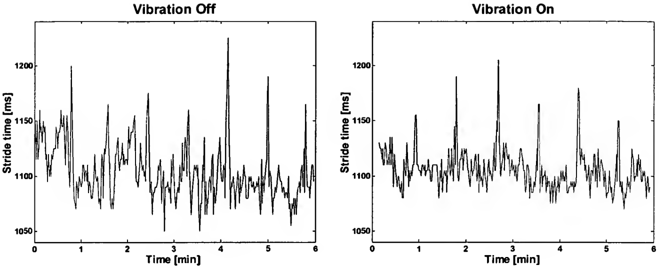

Figure 2. Stride-to-stride interval data obtained from a 41 y/o control subject during vibratory stimulation off (SD 21.46 ms) and on (SD 15.79 ms). The spikes in the stride intervals correspond to turns.

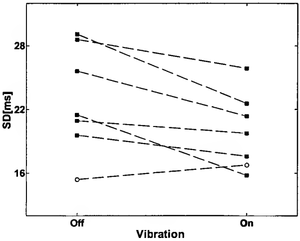

Figure 3. Standard deviation (SD) of the stride-to-stride interval during vibration off and on. Markers connected by a line represent one subject. The black squares represents subjects with decrease of SD during vibration of the soles. The empty circles show a subject with increased SD during vibration stimulation.

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